

APR 18 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	Lorraine R. Pata
Contact Person's Telephone Number:	770-784-6160
Contact Person's Fax:	770-784-6419
Date of Preparation:	March 11, 2005

B. DEVICE NAME:

Trade Name(s):	Sure-Point® Midline Stepping and Stabilization System
Common / Usual Name:	Stepping and Stabilization Device
Classification Names:	90 ITX - Accessory to Diagnostic, Ultrasound transducer 21 CFR 892.5730

C. PREDICATE DEVICE NAME:

Trade Names: Sure-Point® Midline Stepping and Stabilization System

D. DEVICE DESCRIPTION:

The Sure-Point Midline Stepping and Stabilization System is comprised of three components – the Midline Stepping Head with Reusable Needle Template, Midline Articulated Arm with Universal Locking Knob and the Midline Patient Board. The system is situated on a procedure table utilizing the patient's weight on the Midline Patient Board for proper stabilization. The Sure-Point Midline Stepping head is mounted onto the Midline Articulated Arm which in turn is connected to the patient board using mating "dovetail connections", clamps and screws. During a brachytherapy procedure the Midline Stepping head serves to securely hold an ultrasound transducer probe and needle template, while the Midline Articulated Arm with Universal lock facilitates precise three dimensional movements for positioning and placement of radioactive seed implantation.

E. INTENDED USE:

Sure-Point® Midline Stepping and Stabilization Systems are indicated for use to allow precision ultrasound probe alignment and radioactive seed implantation in brachytherapy treatments. A specific application is the treatment of prostate cancer.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject SURE-POINT® MIDLINE Stepping and Stabilization System have the same intended use, design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The appropriate design verification and validation activities for the modification of the SURE-POINT® MIDLINE Stepping and Stabilization System were conducted.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2005

Ms. Lorraine R. Pata
Regulatory Affairs Specialist
C. R. Bard, Inc
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K050724
Trade/Device Name: SURE-POINT® MIDLINE
Stepping and Stabilization System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: ITX and KXX
Dated: March 11, 2005
Received: March 21, 2005

Dear Ms. Pata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K050724

Device Name: SURE-POINT® MIDLINE Stepping and Stabilization System

Indications for Use:

The SURE-POINT MIDLINE Stepping and Stabilization System is indicated for use to allow precision ultrasound alignment and radioactive seed implantation in brachytherapy treatments. A specific application is the treatment of prostate cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1/2/96)

Jane C. Brogan
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050724